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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/392,728 09/09/99 STOCKEMANN

K SCH-1550-C1

EXAMINER

HM22/0829

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ART UNIT

PAPER NUMBER

1617

10

DATE MAILED:

08/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/392,728

Applicant(s)

STOCKEMANN ET AL.

Examiner

Helen Nguyen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 27, 28 and 33-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-26, 29-32 and 47-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

The amendment of paper no. 8 is acknowledged.

Claims 5, 10, 11, 24, and 25 have been amended.

Claims 1-12, 15-26, 29-32 and 47-49 are presented for examination.

The elected species are: A/  $11\beta$ -(4-acetylphenyl)- $17\beta$ -hydroxy- $17\alpha$ -(1-propenyl)estra-4, 9-dien-3-one. B/ Drospirenone (dihydrospirorenone).

The Examiner carefully reviewed the amendment of paper no. 8, The rejections of claims 10-12 and 24-26 of record under 35 U.S.C. 112, second paragraph, 30 and 48 of record under 35 U.S.C. 103(a) are hereby withdrawn in view of the applicant amendment and remarks of paper no. 8.

The claim objection and 35 U.S.C. 102 (a) are maintained.

New ground of rejection is applied.

### Claim objection

Claim 47 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 31. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Therefore, *claim 47 has not been further examined.*

In the amendment of paper no. 8, Applicant overlooked claim 47 and appear to have cancelled claim 49 instead. Appropriate correction is required.

not B/c  
cl. 47  
is canceled  
but obj.  
to cl. 50  
See detail  
in the act B<sub>1</sub>.

***Claim rejection***

The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- Claims 1-12, 15-26, 29-32 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant discloses an amount effective to inhibit ovulation on page 9, lines 22-24 of 2 mg for RU486 and 0.01-30mg for other progesterone antagonists. However, these amounts overlap the ranges disclosed in column 5, lines 15-22 of US Patent 6,225,297 for non-ovulation inhibiting amounts. There appears to be a contradiction because the disclosed amounts effective to inhibit ovulation overlap those ranges disclosed in '297 for non-ovulation.

102/103 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-12, 15-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Stockemann et al., DE 4344463A1 ('463) (see IDS of Feb. 09, 2000).

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Claims 1-12, 15-26 are not novel over the prior art ('463). See page 2, lines 61 to 68, page 3, lines 42 to 44, page 4, lines 1 to 19, page 5, lines 1 to 10, page 6, examples 1 to 3, claims 1, 3, 5, 6, 8, 9, 11 and 12.

- Applicant argues that '297 (the US equivalent) teaches a non-ovulation inhibitor amount of antagonist. However, as discussed above, '297 teaches ranges which reads on Applicant's disclosed amounts.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 15-26, 29-32 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockemann et al., DE 4344463A1 (DE '463) (see IDS of Feb. 09, 2000).

DE '463 is discussed above.

It would have been obvious to use a combination of competitive progesterone antagonist and gestagen as a contraceptive in view of DE '463.

As to the claimed kits, such are well known in the art.

Claims 1-12, 15-26, 29-32 and 47-49 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached on (703) 308-4432 or supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner

August 27, 2001



**EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500**